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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,250	07/30/2003	Stephen D. Pacetti	50623.267	9391

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EXAMINER
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ZACHARIA, RAMSEY E

ART UNIT	PAPER NUMBER
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1773

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/630,250

Applicant(s)

PACETTI ET AL.

Examiner

Ramsey Zacharia

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-24, 26-44 and 54-108 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-20 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-17, 21-24, 26-43 and 54-99 is/are rejected.
- 7) ☒ Claim(s) 44 and 100-108 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>08/10/2005</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Information Disclosure Statement***

2. Reference A1 in the IDS filed 10 August 2005 is lined through because it was already made of record as part of the Office action mailed 23 December 2004.

#### ***Claim Objections***

3. Claim 44 is objected to because of the following informalities: the term "comprises" is repeated on line 14 of the claim. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

4. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 30 is rendered indefinite because it depends from itself.

#### ***Claim Language***

6. For the purpose of examination, claim 30 is taken to depend from claim 21.

***Claim Rejections - 35 USC § 103***

7. Claims 1-4, 6-17, 21-24, 26-43, 54-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eury et al. (U.S. Patent 5,605,696) in view of Heller et al. (U.S. Patent 4,304,767).

Eury et al. is directed to a stent coated with a polymer component capable of carrying and releasing therapeutic drugs (column 1, lines 7-12). The polymer may be a polyorthoester (column 4, lines 37-54).

Eury et al. do not teach the specific structure of the polyorthoester.

Heller et al. is directed to a polymer suitable for use as a drug carrier that may be used to fabricate articles such as implants (column 1, lines 10-20). Not only is the polymer of Heller et al. useful as a drug carrier for applications such as implants, but it can be made by an improved process that has few or none of the disadvantages of conventional polyorthoesters (column 2, lines 34-41). These disadvantages include long reaction times and the formation of volatile condensation products (column 1, lines 64-68), difficulty in achieving high molecular weights (column 2, lines 5-6), occurrence of side reactions leading to impure product (column 2, lines 22-25). The polymer comprises the reaction of a ketene acetal having a functionality of at least two with a polyol (column 2, lines 63-66). The ketene acetal may be a diketene acetal designated by Type I Monomers having a spiro structure in which the terminal R groups can be H or hydrocarbon groups (column 3, lines 25-55). This reads on the diketene acetal of formula (I) in instant claim 3. The polyol may be aliphatic diols, such as those having an alkylene chain of 2 to 12 carbon atoms (column 6, lines 52-67). The polyol may be a polyglycol, such as diethylene glycol or triethylene glycol (column 7, lines 13-20). The polyol may be cycloaliphatic diols,

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such as *cis* and *trans* cyclohexane diols and cyclobutane diol (column 7, lines 21-34). The polyol may also be an aromatic diol, such as 1,4-dihydroxymethylbenzyl (i.e. p-benzenedimethanol) (column 7, lines 46-66).

One skilled in the art would be motivated to use the polyorthoester of Heller et al. as the polyorthoester of Eury et al. because it has few or none of the disadvantages associated with conventional polyorthoesters.

Regarding the numerous individual species of diols recited in the instant claims that are not disclosed by Heller et al., the compounds recited in these claims have very close structural similarities and utilities to those taught by Heller et al. For example, while Heller et al. may not explicitly recite each and every aliphatic diol, not only do Heller et al. teach the broad class of aliphatic diol and but numerous specific examples are provided. As such, a *prima facie* case of obviousness exists based on the similarity in chemical structure and function between the disclosed genera and species of Heller et al. and those recited in the instant claims since there is an expectation that compounds similar in structure will have similar properties. See MPEP § 2144.09.

***Allowable Subject Matter***

8. Claims 18-20 are allowed for the reasons put forth in the action mailed 20 July 2004.
9. Claims 44 and 100-108 would be allowable if rewritten or amended to overcome the objections set forth in this Office action for the reasons put forth in the action mailed 23 December 2004.

***Response to Arguments***

10. Applicant's arguments filed 09 August 2005 have been fully considered but they are not persuasive.

The applicant argues that there is no motivation to combine Eury et al. and Heller et al. Eury et al. is directed to a drug loaded polymeric material for forming a coating on a stent and cites polyorthoester among many different polymers. Heller et al. describe polyorthoesters for forming drug delivery matrices or carriers, which can take many different mechanical or physical forms.

This is not persuasive for the following reasons. Eury et al., while disclosing multiple polymers that may be used as their drug delivery coating, explicitly teach that polyorthoesters may be used. Heller et al. teach a polyorthoester designed to be a drug delivery carrier or matrix. Heller et al. also teach that their polyorthoester has substantial benefits compared to other polyorthoesters (e.g. it can be made by an improved process that has few or none of the disadvantages of conventional polyorthoesters such as long reaction times and the formation of volatile condensation products, difficulty in achieving high molecular weights, and the occurrence of side reactions leading to impure product). Because both Eury et al. and Heller et al. are in the same field of endeavor (biomedical applications) and both are directed to the same problem (drug delivery), the two references can be combined. Furthermore, because Heller et al. provides explicit teachings as to why one skilled in the art would choose to use their polyorthoester as opposed to another polyorthoester, there is also motivation to combine the references. For at least these reasons, the rejection is maintained.

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***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramsey Zacharia whose telephone number is (571) 272-1518. The examiner can normally be reached on Monday through Friday from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney, can be reached at (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Ramsey Zacharia**  
**Primary Examiner**  
**Tech Center 1700**